

In the United States Court of Federal Claims

No. 06-522V
(Filed September 29, 2011)

***** *

ROBERT VERYZER,

Petitioner,

v.

**SECRETARY OF HEALTH
AND HUMAN SERVICES,**

Respondent.

***** *

*

* National Childhood Vaccine
* Injury Act, 42 U.S.C. §§ 300aa-1
* - 300aa-34 (2006); petition for
* review after remand; proof of
* causation in fact; 42 U.S.C.
* § 300aa-12(d)(3)(A)(I); review
* of findings of fact by special
* master.

*

*

*

Alan C. Milstein, Pennsauken, NJ, for petitioner.

Voris E. Johnson, Jr., Washington, DC, with whom was Assistant Attorney General Tony West, for respondent.

MEMORANDUM OPINION AND ORDER

MILLER, Judge.

This case comes before the court on review of a decision after remand. The scope of the remand was narrow, i.e., to make findings of fact and conclusions of law on petitioner's medical records insofar as they were relied upon as proof of causation. See Veryzer v. Sec'y of Health & Human Servs., 98 Fed. Cl. 214, 228 (2011) ("Veryzer III"). ^{1/} The special master implemented the mandate, reopening the record for additional evidence in the process. See Veryzer v. Sec'y of Health & Human Servs., 2011 WL 1935813 (Fed. Cl. Spec. Mstr. Apr. 29, 2011) ("Veryzer IV"). Argument on remand is deemed unnecessary.

^{1/} Veryzer I and Veryzer II were identified in Veryzer III. Both were opinions of the special master then assigned to the case. The earlier granted respondent's motions *in limine* and excluded opinions from two of petitioner's experts; the latter denied petitioner's claim based on the Hepatitis A vaccine.

Petitioner's assignments of error devolve to pressing an erroneous standard for liability—that a petitioner can satisfy his burden of proof with a plausible medical theory that a vaccine caused an injury. Measured against the correct standard—a legally probable (not medically or scientifically certain) medical or scientific explanation that pertains specifically to the petitioner's case, which equates to the tort standard of preponderant evidence—the special master's findings are neither arbitrary nor capricious.

FACTS

The facts before the United States Court of Federal Claims in this review of Special Master Gary J. Golkiewicz's decision on remand largely are unchanged from those previously before this court on review of the special master's order of dismissal. See Veryzer III, 98 Fed. Cl. at 216-21.

Robert Veryzer ("petitioner") was formerly an instructor of business at the [Deleted] and was an Associate Professor at the [Deleted]. Petitioner earned a B.A. from [Deleted], an M.B.A. from [Deleted], and a Ph.D. from [Deleted]. He has authored numerous scholarly articles and a book focusing on [Deleted]. On April 25, 2001, at age forty-one, petitioner received both the Hepatitis A and Hepatitis B vaccinations. Veryzer v. Sec'y of Health & Human Servs., No. 06-0522V, 2010 WL 5185485, at *1 (Fed. Cl. Spec. Mstr. Aug. 9, 2010) ("Veryzer II"). Within hours of the vaccinations, petitioner suffered fever and chills, and within days experienced severe pain and physical injuries, including [Deleted]. Pet. filed July 17, 2006, ¶¶ 17-18 (Fed. Cl. Spec. Mstr.). Petitioner alleges that these injuries caused him to [Deleted]. Id. ¶ 37. All of these injuries petitioner attributes to his vaccinations. Veryzer II, 2010 WL 5185485, at *1. Petitioner originally filed a petition in the Court of Federal Claims pursuant to 42 U.S.C. § 300aa-11 (2000) on September 29, 2003. Petitioner sought compensation due to injuries only caused by the Hepatitis B vaccination because at the time of petitioner's filing the Hepatitis A vaccine had not been added to the Vaccine Injury Table. Id.

Due to difficulty obtaining an expert to testify in support of petitioner's Hepatitis B claim, petitioner on November 2, 2004, withdrew his petition. Veryzer II, 2010 WL 5185485, at *1; see also 42 U.S.C. § 300aa-12(g), -21(b) (permitting petitioner to withdraw petition if special master has not issued decision within 240 days from date petition was filed). "That case was thus concluded without a final order . . . and without entry of judgment on the petitioner's claim for compensation." Veryzer II, 2010 WL 5185485, at *2. A month later, on December 1, 2004, Hepatitis A was added to the Vaccine Injury Table. See National Vaccine Injury Compensation Program: Inclusion of Hepatitis A Vaccines in the Vaccine Injury Table, 69 Fed. Reg. 69,945, 69,945-46 (Dec. 1, 2004) (adding Hepatitis A to Vaccine Injury Table). Petitioner filed suit against the vaccine manufacturer, SmithKline Beecham Corporation, in the United States District Court for the Northern

District of New York, alleging that both the Hepatitis A and Hepatitis B vaccines caused his injuries. Veryzer II, 2010 WL 5185485, at *2. The manufacturer demurred, arguing that, because the Hepatitis A vaccine was now included in the Vaccine Injury Table, petitioner was required first to bring his Hepatitis A claim under the Vaccine Act before he could sue the manufacturer. Id. The district court dismissed petitioner's second suit without prejudice. Id.

On July 17, 2006, petitioner filed a petition in the Court of Federal Claims, claiming entitlement to compensation under the Vaccine Act due to injuries caused by the Hepatitis A vaccine. Pet. at 1, 9. Petitioner's relevant medical records were submitted on March 9, 2007. Petitioner initially obtained a medical expert who opined that the injuries were caused by the Hepatitis B vaccine, not Hepatitis A. Veryzer v. Sec'y of Health & Human Servs., No. 06-0522V, 2008 WL 440298, at *1 (Fed. Cl. Spec. Mstr. Jan. 30, 2008). On April 6, 2007, petitioner moved to amend his petition to include a claim for the Hepatitis B vaccine, which the special master denied pursuant to 42 U.S.C. § 300aa-11(b)(2) and the doctrine of claim preclusion; petitioner was required to rest his petition on a theory that the Hepatitis A vaccination caused his injuries. 2/ Veryzer II, 2010 WL 5185485, at *2. Petitioner obtained expert reports from Drs. Andrew Moulden, M.D., Ph.D., and Sherri Tenpenny, D.O. Dr. Moulden concluded that petitioner's injuries were the result of the eponymous "Moulden Anoxia Spectra Syndrome," or "M.A.S.S. response," which resulted from the Hepatitis A vaccination and caused neurological, physiological, and functional damage to petitioner. Pet'r's Br. filed Aug. 27, 2008, Ex. 2 at 112, ECF No. 36 (Fed. Cl. Spec. Mstr.) (the "Moulden Report"); see also Veryzer v. Sec'y of Health & Human Servs., No. 06-0522V, 2010 WL 2507791, at *3, *26 (Fed. Cl. Spec. Mstr. June 15, 2010) (excluding opinions of two experts for petitioner) ("Veryzer I").

Respondent filed two motions *in limine* seeking to exclude these experts' opinions, and Special Master Richard B. Abell granted the motions, Veryzer I, 2010 WL 2507791, at *26, a decision that was subsequently upheld in Veryzer III, 98 Fed. Cl. at 225. Thereafter, petitioner moved for a ruling on the written record, which Special Master Abell granted. On August 9, 2010, the special master issued a decision denying compensation and dismissing the petition. Veryzer II, 2010 WL 5185485, at *1. This court reviewed that decision pursuant to petitioner's motion for review and remanded the matter because the special master failed to make factual findings that adequately articulate his reasons for concluding that petitioner's medical records are insufficient to establish a medical theory causally

2/ Petitioner did not appeal the special master's decision denying his motion to amend to include a claim based on the Hepatitis B vaccine. Veryzer IV, 2011 WL 1935813, at *4. Consequently, petitioner cannot now challenge that decision, and his petition is limited to claims arising from the Hepatitis A vaccine only.

connecting petitioner's injuries to the Hepatitis A vaccination. Veryzer III, 98 Fed. Cl. at 227.

PROCEEDINGS ON REMAND

On remand this matter was assigned to Special Master Golkiewicz after Special Master Abell retired. The special master was tasked to make "findings of fact and conclusions of law concerning petitioner's medical records." Id. at 228. Although not required to do so, the special master reopened the record for additional evidence. See Veryzer IV, 2011 WL 1935813, at *7-*8. At an initial status conference, petitioner indicated that he would submit additional medical records. Id. at *7. The special master entered an order governing the schedule of proceedings, and petitioner filed a notice stating his intent to rely on a letter report from his treating physician, Manuel Astruc, M.D. Id. Respondent filed a status report and explained that Dr. Astruc's report revealed a change in his opinion as to causation and lacked information that was necessary for petitioner to establish his claim, thus preventing respondent from determining whether or not a responsive expert was needed. Id. To resolve this uncertainty, six questions were posed to Dr. Astruc—four prepared by respondent and two prepared by the special master. Id. Petitioner informed respondent and the special master that answers would be provided in petitioner's brief, disregarding the special master's cautionary note that the "lawyer's explanations are not a substitute for the expert's elucidation of causation." Id. (citation omitted) (internal quotation marks omitted). Both parties filed supplemental memoranda and declined the special master's invitation for further proceedings, instead acknowledging that the case was ripe for decision. Id. at *8.

On April 29, 2011, the special master issued a comprehensive opinion in which he separately addressed and analyzed the medical records and reports on which petitioner relied. This undertaking led the special master to make a number of general findings as to the probative value of petitioner's evidence, contributing to his ultimate conclusion that "petitioner has failed to provide preponderant evidence that he suffered a vaccine-related injury due to the Hepatitis A vaccine." Id. at *25. The special master first noted his "overarching observation" that, although "petitioner engaged numerous doctors shortly after vaccination[,] . . . there was no consensus that petitioner's complaints were vaccine-related." Id. at *8. He explained that, despite notations in some records stating that petitioner reacted to the vaccine, no doctor made this sweeping conclusion after testing and examination; rather, this information was often provided to the examining physician by the petitioner at the outset of the examination, and a notation was made in order accurately to document petitioner's complaints. Id. at *9, *13. Alternatively, the special master found that, to the extent the physicians' reports contemplated the possibility of vaccine relatedness, they were often hypothesizing on matters outside their specialties and "merely raising the possibility that petitioner's answers lie with another specialist." Id. at *8.

Second, the special master observed that “[p]etitioner repeatedly pulls out of context any reference to the immunization as evidence of causation,” id. at *14, such that a review of the relied-upon report as a whole entirely nullifies its purported value as advanced by petitioner. For instance, in petitioner’s supplemental brief, he references Dr. Bruce A. Beesley’s statement that petitioner “may have had an autoimmune reaction from the vaccine. This could have caused some mild demyelination.” Id. at *12 (citation omitted) (internal quotation marks omitted). Exemplifying his thorough review of petitioner’s medical records and expert reports, the special master noted that this statement was followed immediately by Dr. Beesley’s observation that “I find almost nothing on exam that would suggest [demyelination].” Id. (citation omitted) (internal quotation marks omitted). Dr. Beesley also explained that he “entertained the possibility of purely autonomic dysfunction as a result of the inflammation from the vaccination but . . . there are no systemic symptoms.” Id. (citation omitted) (internal quotation marks omitted). Thus, although vaccine relatedness may have been mentioned by physicians and experts, such statements often were of little value for the reasons heretofore noted and properly were not considered preponderant evidence by the special master.

The special master adopted respondent’s view that petitioner’s treating physicians were doubtful that petitioner’s conditions were vaccine-related or, if they did entertain the idea of relatedness, they did so on account of the temporal proximity between petitioner’s receipt of the vaccine and the onset of his symptoms. Id. at *16. Moreover, none of the physicians “offer[ed] a probable medical theory linking the Hep A vaccine specifically to petitioner’s symptoms.” Id. (citation omitted) (internal quotation marks omitted). To the contrary, where a medical theory was offered, it often implicated the Hepatitis B vaccine or a combination of both vaccines. Specifically, petitioner contends that, due to the vaccine, he suffered thimerosal (mercury) toxicity. Id. at *21. Dr. Lionel D. Alboum’s opinion supports petitioner’s contention that he suffered from mercury toxicity. Id. at 14. However, as the special master pointed out, although the Hepatitis B vaccine contained thimerosal, which could lead to mercury toxicity, the Hepatitis A vaccine never did, and petitioner did not provide evidence indicating that the Hepatitis A vaccine can cause mercury toxicity. Id. at *21.

The special master acknowledged instruction from the United States Court of Appeals for the Federal Circuit that “[e]vidence from a treating physician can be ‘quite probative since treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect shows that the vaccination was the reason for the injury.’” Id. at *16 (quoting Andreu v. Sec’y of the Dep’t of Health & Human Servs., 569 F.3d 1367, 1375 (Fed. Cir. 2009)). The special master further recognized that, because “‘treating physicians [often] do not elaborate on medical theories of causation in medical records because they are not relevant to the clinician’s agenda, which is to identify, treat, and heal,’” id. at *17 (quoting Capizzano v. Sec’y of the Dep’t of Health & Human Servs., No. 00-759V,

2006 WL 3419789, at *6 (Fed. Cl. Spec. Mstr. Nov. 8, 2006)), “it is generally necessary to . . . have the treating physician expand in reports and testimony regarding what is stated in the medical records,” id. at *17. With this in mind, the special master undertook a review of the medical records of petitioner’s treating physician, Dr. Astruc, as well as a supplemental opinion in which Dr. Astruc responded to the six questions posed to him.

Overall, the special master deemed Dr. Astruc’s opinion “vague[] and insufficien[t],” commenting that Dr. Astruc failed to reference any of petitioner’s medical records. Id. at *20. Specifically, the special master stated that

[a]ny explanation or theory as to how the Hepatitis A vaccine can cause heavy metal toxic exposure or demyelination is lacking. Without reference to petitioner’s medical records, Dr. Astruc fails to show how petitioner’s presentation fits a logical sequence of cause and effect showing the vaccine caused his alleged injuries. . . . [Finally,] Dr. Astruc states he is not qualified to opine on the appropriate time from vaccine to onset of petitioner’s symptoms in the case of demyelination. . . . [This] calls into question whether he is qualified to opine regarding a theory and logical sequence of cause and effect regarding demyelination.

Id. The special master concluded: “Dr. Astruc’s reports add[ed] very little qualitatively to petitioner’s evidence on causation” Id. Based on his review and analysis, the special master denied compensation.

On May 25, 2011, petitioner filed a motion for review. Petitioner urges the court to overturn the special master’s decision based on four errors. First, petitioner contends that the special master applied an overly strict construction of Althen v. Secretary of Health & Human Services, 418 F.3d 1274 (Fed. Cir. 2005), in finding that petitioner did not meet his burden of proof on causation. Pet’r’s Br. filed May 25, 2011, at 2. Second, petitioner argues that the special master applied a heightened standard of proof to Althen’s second prong by relying on the absence of test results showing that petitioner reacted to the Hepatitis A vaccine as a means to conclude that petitioner did not show a logical sequence of cause and effect between the vaccine and the injury, thereby requiring proof of medical certainty. Id. at 14. Next, petitioner challenges the special master’s finding that petitioner failed to demonstrate a temporal relationship between receipt of the vaccine and onset of symptoms, contending that his records depict him as healthy pre-vaccination and symptomatic post-vaccination. Id. at 15. Finally, petitioner contends that the special master erred in disregarding references to the Hepatitis B vaccine and both vaccines together. Id. at 16.

DISCUSSION

I. Standards

1. Standard of review

The National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1 to 300aa-34 (2006) (the “Vaccine Act”), specifies three alternative courses of action available to the Court of Federal Claims in reviewing a special master’s decision. The court may

- (A) uphold the findings of fact and conclusions of law of the special master and sustain the special master’s decision,
- (B) set aside any findings of fact or conclusions of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or
- (C) remand the petition to the special master for further action in accordance with the court’s direction.

42 U.S.C. § 300aa-12(e)(2).

In Capizzano v. Secretary of Health & Human Services, 440 F.3d 1317 (Fed. Cir. 2006), the Federal Circuit observed that, in appeals of Court of Federal Claims decisions in Vaccine Act cases, the Federal Circuit “review[s] the trial court’s legal determination that the special master acted in a manner not in accordance with law *de novo*,” *id.* at 1323-24 (quoting Althen, 418 F.3d at 1277-78), and also “determine[s] anew whether the . . . special master’s findings of fact were arbitrary or capricious,” Capizzano, 440 F.3d at 1324 (citing Lampe v. Sec’y of Health & Human Servs., 219 F.3d 1357, 1360 (Fed. Cir. 2000)). This scope of review necessarily results in the Federal Circuit’s applying the same standard of review to a special master’s decision as the Court of Federal Claims does in reviewing the same. Capizzano, 440 F.3d at 1323-24 (“In an appeal from a decision of the Court of Federal Claims in a Vaccine Act case, we apply the same standard of review that the Court of Federal Claims applied to the special master’s decision.”). More recently, in Lombardi v. Secretary of Health & Human Services, No. 2011-5004, 2011 WL 3890521, at *6 (Fed. Cir. Sept. 6, 2011), the Federal Circuit recognized that, although it was reviewing the Court of Federal Claims’s decision under the non-deferential *de novo* standard on both legal 3/ and factual

3/ Petitioner characterizes his challenge to whether the special master applied the appropriate theory of causation as predicated on arbitrariness and capriciousness. Recognizing that this is a legal question, *see Lombardi*, 2011 WL 3890521, at *6, the court has reviewed the standard applied by the special master both as a matter of law and as applied to the facts.

issues, it was actually reviewing the special’s master’s factual findings under the deferential arbitrary and capricious standard—the same standard applied by the Court of Federal Claims when it first reviews the special master’s decision. Id. All this is a prelude to reciting the degree of deference accorded to special masters’ findings of fact that is a product of their special expertise as administrative factfinders who are not bound to apply the Federal Rules of Evidence or otherwise engage in traditional trial-type proceedings.

The deferential “arbitrary and capricious” standard, see 42 U.S.C. § 300aa-12(e)(2)(B); de Bazan v. Sec’y of Health & Human Servs., 539 F.3d 1347, 1350-51 (Fed. Cir. 2008) (citing 42 U.S.C. § 300aa-12(e)(2)), is “uniquely deferential.” Doe v. Sec’y of Health & Human Servs., 601 F.3d 1349, 1355 (Fed. Cir. 2010) (citing Hodges v. Sec’y of Dep’t of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993)); see also Masias v. Sec’y of Health & Human Servs., 634 F.3d 1283, 1287 (Fed. Cir. 2011) (noting that “[a]rbitrary and capricious is a highly deferential standard of review”); Munn v. Sec’y of Dep’t of Health & Human Servs., 970 F.2d 863, 869-70 (Fed. Cir. 1992) (noting that arbitrary and capricious standard is “well understood to be the most deferential possible”); Hines v. Sec’y of Dep’t of Health & Human Servs., 940 F.2d 1518, 1528 (Fed. Cir. 1991) (upholding Court of Federal Claims’s conclusion that special master’s decision was not arbitrary and capricious, noting that “‘arbitrary and capricious’ is a highly deferential standard of review”). The Federal Circuit in Broekelschen v. Secretary of Health & Human Services, 618 F.3d 1339, 1345 (Fed. Cir. 2010), cited the standard applied in Hines with approval, agreeing that the standard of review was highly deferential. See Broekelschen, 618 F.3d at 1348 (explaining the “‘extreme[] difficult[y]’” of demonstrating reversible error “if the special master ‘has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision’” (quoting Hines, 940 F.2d at 1528)).

Discretionary rulings of the special master, such as the exclusion of evidence, are reviewed under the abuse of discretion standard. Cedillo v. Sec’y of Health & Human Servs., 617 F.3d 1328, 1338 (Fed. Cir. 2010); Munn, 970 F.2d at 870 n.10. While the special master may apply the standards for admissibility of scientific evidence articulated in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993) (interpreting trial judge’s role in admitting scientific evidence offered under Fed. R. Evid. 702), the special master may not cloak credibility determinations as exclusions under Daubert or thereby render his findings arbitrary and capricious. See Moberly v. Sec’y of Health & Human Servs., 592 F.3d 1315, 1326 (Fed. Cir. 2010) (“Finders of fact are entitled—indeed, expected—to make determinations as to the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence. What [is] prohibited [i]s for the finder of fact to reject evidence based on an unduly stringent legal test while characterizing the rejection as based on the reliability of particular evidence or the credibility of a particular witness.”); see also Cedillo, 617 F.3d at 1338 (opining that special masters may apply Daubert factors to evaluate reliability of expert witnesses’ opinions and methodologies);

Terran v. Sec’y of Health & Human Servs., 195 F.3d 1302, 1317 (Fed. Cir. 1999) (finding no error in special master’s use of Daubert factors as tool for evaluating reliability of scientific evidence in Vaccine Act cases); Hodges, 9 F.3d at 967 (Newman, J., dissenting) (explaining that special master erred in failing to apply Daubert and consider scientific evidence, explaining that “[w]hen resolution of a legal issue requires the finding of scientific fact, the trier of fact must assess the methodology on which the scientific evidence and opinion is grounded, and ascertain the weight to which the finding is entitled). Compare Broekelschen, 618 F.3d at 1350 (affirming special master’s decision despite fact that special master may have improperly considered expert’s demeanor because special master provided a number of additional reasons why that expert’s opinion was “better supported by sound medical explanation”), with id., 618 F.3d at 1353 (Mayer, J., dissenting) (“[C]redibility determinations can be used to determine if an expert is reliable, but weighing the persuasiveness of the competing medical theories is a separate analysis. Once the special master determined both experts were highly qualified and reliable, there was no reason for him to give any additional weight to the background or demeanor of the government’s expert.”).

2. Proving causation in Vaccine Act cases

To be compensated under the Vaccine Act, petitioners must prove that an injury was caused by a vaccine listed on the Vaccine Injury Table set forth in 42 U.S.C. § 300aa-14. See id. § 300aa-11(c)(1)(A), (C); de Bazan, 539 F.3d at 1351. The Vaccine Injury Table, 42 U.S.C. § 300aa-14(a), “lists symptoms and injuries associated with each listed vaccine and a timeframe [*sic*] for each symptom or injury.” de Bazan, 539 F.3d at 1351. Petitioners can meet the causation burden in one of two ways. Walther v. Sec’y of Health & Human Servs., 485 F.3d 1146, 1149 (Fed. Cir. 2007). If petitioners demonstrate that the injury falls under the Vaccine Injury Table within the time frame prescribed by the Table (a “Table injury”), causation is presumed. See 42 U.S.C. § 300aa-14(a); Walther, 485 F.3d at 1149. Alternatively, if the injury is not included on the Vaccine Injury Table, or falls outside the prescribed time frame for the symptom to occur (an “off-Table injury”), petitioners must prove by a preponderance of the evidence that the vaccine was the cause in fact of the injury. See 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I); Walther, 485 F.3d at 1149; see also Shyface v. Sec’y of Health & Human Servs., 165 F.3d 1344, 1350 (Fed. Cir. 1999). The case *sub judice* is of this latter type, involving an off-Table injury requiring petitioner to prove causation in fact. To meet this burden, a claimant must satisfy the Althen test by offering (1) a medical theory causally connecting the vaccination and the injury, (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury, and (3) a showing of a proximate temporal relationship between vaccination and injury. Althen, 418 F.3d at 1278.

Indulgence is requested for a further peroration, which, it is hoped, will explain the narrow focus of the court's review. Over the past two years, something has leached into the review process undertaken by the Court of Federal Claims in reviewing special masters' decisions pursuant to the Vaccine Act. A number of review decisions represent full *de novo* reviews, with findings of fact and conclusions of law supplied by the Court of Federal Claims. Two justifications underlie this approach to review: the reviewing court's opinion that the special master has cloaked arbitrary and capricious findings of fact in credibility determinations or its opinion that the special master has imposed a heightened burden of proof, sometimes referred to as a showing of causation to the level of medical or scientific certainty. Framing the standard as whether the condition was "likely caused" by the vaccine has led to invocation of the standard "plausible," as in "a plausible medical theory," which has come to be shorthand for the relaxed standard of proof envisioned by the Vaccine Act. Yet, since 2010, the Federal Circuit has stated unequivocally that "proof of a 'plausible' or 'possible' causal link between the vaccine and the injury . . . is not the statutory standard." Moberly, 592 F.3d at 1322. The correct standard for causation is proof of legal probability. Id. (citing Knudsen v. Sec'y of Dep't of Health & Human Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994)); accord Broekelschen, 618 F.3d at 1345.

It could well be that the word "plausible" fits more comfortably into the scientific lexicon than the legal. Whether a theory of causation is "biologically plausible," Andreu, 569 F.3d at 1375, or "medical[ly] plausib[le]," Althen, 418 F.3d at 1278, or whether the term applies to a legal theory, i.e., evidence "not wholly implausible," Cedillo, 617 F.3d at 1338 (citing Lampe, 219 F.3d at 1363), or is a mixture of both, i.e., "draw[ing] plausible inferences," Lampe, 219 F.3d at 1360 (citing Hines, 940 F.2d at 1528), and a "plausible theor[y] of causation," id. at 1368, the concept of plausibility has eluded a consistent role in Vaccine Act cases.

A synthesis of the recent Federal Circuit opinions addressing this issue indicates that plausible causation relates to evaluation of Althen's first prong, which is satisfied by a "biologically plausible theory." See Andreu, 569 F.3d at 1375 (concluding that petitioner satisfied Althen's first prong by offering "biologically plausible" theory linking vaccine and injury); Pafford v. Sec'y of Health & Human Servs., 451 F.3d 1352, 1356-57 (Fed. Cir. 2006) (determining that petitioner presented medical theory causally connecting vaccine and injury because it was "biologically plausible that one or more of the vaccinations at issue could cause" petitioner's condition). See generally Moberly, 592 F.3d at 1322 (providing that a petitioner can satisfy Althen's first prong by "provid[ing] a reputable medical or scientific explanation that . . . need only be 'legally probable, not medically or scientifically certain.'" (quoting Knudsen, 35 F.3d at 548-49)).

Once plausibility is confined properly to general causation—the biological or medical theory put forward—Althen's second prong turns to examining specific or legal causation:

whether the vaccine caused petitioner's injury or illness. See Pafford, 451 F.3d at 1356. The standard is not "conclusive proof," see Andreu, 569 F.3d at 1377; rather, a petitioner must prove by a preponderance of evidence that the vaccine was a substantial factor in causing the illness or injury. Shyface, 165 F.3d at 1352. The Federal Circuit summarized the proper analysis and standards in Moberly, explaining that, "[t]o prove causation [in an off-Table injury case], a petitioner in a Vaccine Act case must show that the vaccine was 'not only a but-for cause of the injury but also a substantial factor in bringing about the injury.'" Moberly, 592 F.3d at 1321-22 (quoting Shyface, 165 F.3d at 1352-53). A petitioner can make this showing by satisfying the three Althen factors, thus demonstrating by a preponderance of the evidence that the vaccine caused the injury. Moberly, 592 F.3d at 1322.

Applying the Federal Circuit's governing standard for determining causation in an off-Table injury case, this court is now tasked with reviewing the special master's decision to deny compensation under the arbitrary and capricious standard set forth in 42 U.S.C. § 300aa-12(e)(2)(B).

II. Petitioner's assignments of error ^{4/}

1. Theory of causation

Petitioner submits that the special master's finding that petitioner did not meet his burden of providing a legally probable—but not medically or scientifically certain—medical theory establishing that the Hepatitis A vaccination caused his condition is arbitrary and capricious. According to petitioner, his medical records, as well as Dr. Astruc's reports and supplemental opinions, are replete with notations that the Hepatitis A and B vaccines can cause injuries of the type experienced by petitioner. Specifically, petitioner faults the special master for disregarding Dr. Astruc's conclusion that he could find "no other cause [aside from the vaccinations] . . . for petitioner's condition" simply because Dr. Astruc specializes in psychiatry and did not reference petitioner's medical records. Pet'r's Br. filed May 25, 2011, at 7. This specialty, petitioner contends, enabled Dr. Astruc to rule out an emotional cause for petitioner's symptoms, and, in the absence of exposure to other elements that could cause such symptoms, only the vaccines remain as a potential cause. Petitioner then lists notations in various reports purporting to implicate the vaccines as the cause of petitioner's

^{4/} Petitioner's memorandum in support of his motion for review outlined four reasons why the court should overturn the special master's decision to deny compensation. See generally Pet'r's Br. filed May 25, 2011. Petitioner made a number of arguments in support of these four reasons. Although the four headings in this opinion do not correspond with petitioner's, they allow the court to more cogently address the arguments made by petitioner and respondent.

ailments. Even recognizing that the special master found that many of these notations were mere recordations of information that petitioner had provided to the various physicians, petitioner contends that this determination “is not based in fact or supported by any affidavit or record.” Id. at 14. Finally, petitioner argues that, despite the physicians’ conclusions, respondent has not come forward with a “countervailing opinion or explanation as to what was the cause of petitioner’s disability.” Id. at 3.

Respondent rejoins that the special master applied the proper standard to Althen’s first prong and concluded that “petitioner failed to present preponderant evidence of a theory of causation that was legally probable.” Veryzer IV, 2011 WL 1935813, at *22. It argues that the special master reached this conclusion after conducting “a complete and objective analysis of the medical records,” ensuring that all theories posited by petitioner’s many physicians were considered. Resp’t’s Br. filed June 24, 2011, at 18 (quoting Veryzer IV, 2011 WL 1935813, at *22). Although some of petitioner’s medical records referenced the Hepatitis A vaccine as a cause of petitioner’s condition, respondent points out that the special master’s review revealed that such references did not follow an examination of petitioner; rather, they resulted from conversations with petitioner or pure conjecture by physicians considering possible causes outside their realms of expertise. Respondent explains that, while petitioner relies on these interstitial, conclusory references, he fails to identify any record or opinion that establishes a legally probable theory as required by Althen. Moreover, according to respondent, petitioner’s argument indicates mere disagreement with the special master’s well-reasoned findings.

Upon review of the special master’s decision on remand, the court finds that the special master’s conclusion that petitioner failed to satisfy Althen’s first prong was neither arbitrary nor capricious. The special master undertook an exhaustive review of petitioner’s medical records and separately set forth his findings as to each record. See Moberly, 592 F.3d at 1323-24 (finding that special master and Court of Federal Claims “undertook a meticulous review of [petitioner]’s medical records” such that conclusion that no causal link existed between vaccine and injury was not arbitrary and capricious). The special master acknowledged statements purporting to deem the vaccines the cause of petitioner’s symptoms. However, after considering the entirety of each report in which such statements were made, the special master determined that they were recordations of information conveyed to the physicians by petitioner, possibilities raised by physicians who believed the answer was outside their specialty, or opinions based solely on the time from receipt of the vaccines to onset of symptoms. No consensus emerged supporting petitioner’s theory that the Hepatitis A vaccine caused his condition. To the contrary, where a medical theory was offered, it implicated the Hepatitis B vaccine, which was not part of petitioner’s claim. Consequently, the special master noted that none of the physicians “offer[ed] a probable medical theory linking the Hep A vaccine specifically to petitioner’s symptoms.” Veryzer IV, 2011 WL 1935813, at *16 (citation omitted) (internal quotation marks omitted). The

special master arrived at his conclusion after reviewing the entire record; therefore, his determination that none of the reports or opinions drew a causal link between the vaccine and the injury so as to establish a legally probable medical theory of causation is not arbitrary or capricious.

Petitioner argues that, despite the special master's concession that petitioner's medical records implicate the Hepatitis B vaccine or a combination of the Hepatitis A and B vaccines, he refused to consider such evidence in determining whether petitioner established a medical theory connecting the vaccines to petitioner's injury. Dr. Alboum opined that petitioner's condition resulted from thimerosal (mercury) toxicity. This suggests a link between the Hepatitis B vaccine, which contains mercury, and petitioner's condition. Petitioner further notes that in addition to connecting the mercury in Hepatitis B to the mercury poisoning likely suffered by petitioner, Dr. Alboum also explained that other materials, such as aluminum, in both vaccines may have been detrimental.

Respondent defends the special master's not addressing any references to the Hepatitis B vaccine as beyond the scope of this court's remand order. See Veryzer III, 98 Fed. Cl. at 216 (acknowledging special master's denial of petitioner's motion to amend his petition to include a claim based on the Hepatitis B vaccine). In his first motion for review, petitioner failed to challenge Special Master Abell's denial of his motion to include in his current petition claims based on the Hepatitis B vaccine. As a result, respondent remits petitioner to the consequence of his failure to preserve the issue for consideration by the Court of Federal Claims, and the issue of whether such denial was in error was not before the undersigned in Veryzer III.

This court agrees with respondent that claims based on the Hepatitis B vaccine are not properly the subject of this motion for review. Consequently, the special master's rejection of medical theories relying on the Hepatitis B vaccine, such as thimerosal toxicity, did not amount to a legal error, nor was it arbitrary or capricious. Although Dr. Alboum indicated that other materials in the two vaccines could be detrimental, petitioner and Dr. Alboum did not offer a theory connecting any materials other than mercury, which is not found in the Hepatitis A vaccine, to petitioner's condition. As such, the special master's decision reflected a rational basis for his conclusion that "petitioner failed to present preponderant evidence of a theory of causation that was legally probable." Veryzer IV, 2011 WL 1935813, at *22.

2. Application of Althen's second prong in determining specific causation

Petitioner contends that the special master "applied an overly strict construction" of Althen's second prong. Pet'r's Br. filed May 25, 2011, at 14. The special master noted an absence of test results indicating that petitioner had an abnormal reaction to the Hepatitis A

vaccine. Petitioner interprets this to mean that the special master sought proof of medical certainty that a cause-and-effect relationship existed between the vaccine and petitioner's symptoms. Because medical certainty is not the standard, petitioner argues that the special master's reliance on the absence of test results in finding that petitioner had not satisfied Althen's second prong rendered his decision arbitrary and capricious. Respondent, however, explains that the special master's reference to a lack of test results "was one piece of evidence, in addition to other kinds of evidence, that petitioner had failed to produce to support his claim." Resp't's Br. filed June 24, 2011, at 13 n.5.

The absence of test results was not the *sine qua non* of the special master's decision, which is shown by the special master's review of petitioner's medical records. The remand order instructed the special master to make findings of fact regarding petitioner's medical records. The special master reviewed each individual medical record. He separately explained the contents of each record in finding that, cumulatively, they did not amount to preponderant evidence of causation. Petitioner argues that the special master dismissed evidence that did not support the conclusion that the special master sought to reach. Instead of substantiating this charge, petitioner chides respondent for its failure to submit an alternative explanation as to what caused petitioner's condition. However, an alternative theory is not required unless and until petitioner carries his burden of providing preponderant evidence of causation by satisfying the Althen test. See Althen, 418 F.3d at 1278 ("If [a claimant] satisfies this burden, she is 'entitled to recover unless the [government] shows, also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine.'" (quoting Knudsen, 35 F.3d at 547 (second alteration in original) (citation omitted))).

The special master properly assessed the probative value of the statements provided by petitioner's physicians, explaining why those statements do not demonstrate a logical sequence of cause and effect showing that the vaccine caused injury. The special master discovered that petitioner's physicians doubted that his condition was vaccine-related. When physicians entertained the idea of vaccine-relatedness, the "driving factor" was the fact that petitioner's condition developed post-vaccination. Veryzer IV, 2011 WL 1935813, at *16. Moreover, many statements that petitioner relies on were made by physicians who were acting outside their areas of expertise and were proffering possibilities to be explored by qualified specialists in those areas. The reports not only fail to establish a medical theory of causation, but they also offer inconsistent causes of petitioner's condition.

In Veryzer III this court noted that "[t]he medical records offer inconsistent indications of possible causes, which the fact finder may deem inconclusive and not a demonstration of a 'logical sequence of cause and effect showing that the vaccination was the reason for the injury.'" 98 Fed. Cl. at 227 (quoting Althen, 418 F.3d at 1278). Petitioner disagrees and asserts that, when read as a whole, his medical records "provide both

inferentially and expressly the conclusion that petitioner had a serious and continuing reaction to the Hepatitis A and B vaccines.” Pet’r’s Br. filed May 25, 2011, at 5. Again, petitioner cites stray sentences from various medical reports, disregarding the special master’s observations that such sentences, taken in context, do not support a medical theory of causation.

As noted above, the special master determined that none of petitioner’s physicians offered a legally probable medical theory causally connecting the Hepatitis A vaccine to petitioner’s symptoms. Absent such a theory, a logical sequence of cause and effect showing that receipt of the Hepatitis A vaccine led to petitioner’s condition could not be shown. The special master relied on the deficiencies that he observed in the contents of petitioner’s records and not solely on the absence of medical test results. This court concludes that the special master did not apply a standard of medical certainty. Instead, the special master conducted a thorough review of all evidence and merely noted the absence of test results as one piece of evidence among many that prevented petitioner from satisfying Althen’s second prong. Given the special master’s careful review and application of the appropriate standard, the special master’s ultimate finding that petitioner did not show a logical sequence of cause and effect is neither arbitrary nor capricious.

3. Temporal relationship between Hepatitis A vaccine and injury

Petitioner argues that the special master’s conclusion that he failed to show a temporal relationship between the vaccine and injury is arbitrary and capricious. Petitioner received the vaccines at the age of forty-one. His medical history up to that point in time is devoid of the cognitive impairments from which he now suffers. Petitioner also contends that in Veryzer III this court concluded that petitioner had satisfied Althen’s temporal proximity prong. See Veryzer III, 98 Fed. Cl. at 227 (“Petitioner has shown a ‘temporal relationship’ between his vaccinations and the first manifestation of his injuries.”). Petitioner, however, fails to consider what follows the quoted sentence. This court explained that a temporal relationship alone will not demonstrate the requisite causal link and that petitioner must posit a medical theory causally connecting vaccine and injury. Id.

As de Bazan indicates, the “etiology” of the disorder determines the appropriate temporal relationship. de Bazan, 539 F.3d at 1352. Merely showing that injury occurred after administration of a vaccine is insufficient. Thus, as respondent correctly points out, this court recognized the literal temporal relationship between receipt of the vaccine and the onset of petitioner’s symptoms. It did not find a temporal relationship with respect to a particular medical theory, as de Bazan instructs. See id. (“[T]he proximate temporal relationship prong requires preponderant proof that the onset of symptoms occurred within a timeframe [*sic*] for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact.”).

The special master explained that petitioner proposed two medical theories—demyelination and thimerosal toxicity—causally connecting Hepatitis A to his condition. He noted that petitioner’s symptoms occurred within hours of receiving the vaccinations. What is missing, however, is any evidence that either of these theories would result in symptom onset within mere hours of vaccination. Absent such evidence, the special master’s finding that petitioner could not meet his burden of proving an appropriate temporal relationship is not arbitrary or capricious.

Even if Veryzer III did conclude that petitioner satisfied Althen’s third prong, the ruling would not stand as the law of the case because the temporal association must relate to the pathology of the specific medical theory alleged to have caused the injury. In Veryzer III the undersigned mentioned the special master’s finding that the record did not establish a plausible medical theory causally connecting the vaccine and the alleged injuries. Absent such a showing, a temporal association cannot be demonstrated.

4. Sufficiency of Dr. Astruc’s opinion letters to satisfy petitioner’s burden

Petitioner’s arguments regarding Dr. Astruc’s opinion are inconsistent. First, petitioner notes that the Federal Circuit has often placed much emphasis on statements from treating physicians—like Dr. Astruc—deeming that these physicians are often in the best position to resolve causation issues. See Cedillo, 617 F.3d at 1347 (quoting Capizzano, 440 F.3d at 1326). Because these physicians are concerned with treating and healing, their reports often do not expound on theories of causation. Petitioner thus contends that special masters and the Court of Federal Claims are permitted to draw inferences from medical records, thereby seeming to imply that treating physicians need not address causation specifically in their reports. On the other hand, however, petitioner laments that the special master’s opinion focuses too heavily on Dr. Astruc’s opinion. Respondent counters that it was petitioner who brought Dr. Astruc’s opinions to the fore by submitting supplemental reports from him to address the Althen factors.

The special master noted that Dr. Astruc is a psychiatrist and does not specialize in neurology or toxicology. As a result the special master questioned Dr. Astruc’s ability to rule out non-psychiatric causes of petitioner’s condition. Veryzer IV, 2011 WL 1935813, at *18. Petitioner responds that Dr. Astruc ruled out an emotional cause, as he is qualified to do, and relied on the opinions of other physicians in ruling out other causes, as he is entitled to do, leaving only the Hepatitis A and B vaccines as the cause or causes of petitioner’s condition. Given Dr. Astruc’s conclusion, supplemented by the opinions of petitioner’s other physicians, petitioner argues that the special master erred in finding this evidence insufficient to satisfy Althen in the absence of an opposing expert report or alternative theory of causation from respondent. Respondent resists the need to produce such evidence. According to respondent, the burden would shift to respondent only if petitioner satisfied his

burden of providing preponderant evidence of causation, thus satisfying the Althen test. See Althen, 418 F.3d at 1278.

Because the special master concluded that petitioner did not meet his burden, the burden never shifted to respondent to provide an alternative explanation. In finding that petitioner had failed to meet his burden, the special master relied on deficiencies in petitioner's medical records and the vagueness of Dr. Astruc's supplemental reports. These factual findings are accorded great deference—"the Court of Federal Claims is not to second guess the Special Masters [*sic*] fact-intensive conclusions; the standard of review is uniquely deferential for what is essentially a judicial process." Hodges, 9 F.3d at 961. In Hodges the Federal Circuit noted that the special master had rejected petitioner's medical theory causally connecting the vaccine and the alleged injury. Because "nothing . . . suggest[ed] that the Special Master failed to comprehend the value or effect of the medical evidence," the court gave deference to his findings and affirmed the decision. Id. at 961-62. The special master's exhaustive explanation of each physician's findings and conclusions in the case at bar similarly gives no indication that he "failed to comprehend the value or effect of the medical evidence." Id. Thus, respondent's failure to offer opposing theories or alternative explanations does not, on its own, render the special master's decision arbitrary and capricious, particularly where, as here, the special master demonstrated a clear understanding of the import of the medical records and opinions.

Petitioner also has argued that the special master relied too heavily on Dr. Astruc's testimony, "such that petitioner's claim would succeed or fail on the extent to which the Special Master found him persuasive." Pet'r's Br. filed May 25, 2011, at 6. What petitioner fails to note, however, is that he opted to submit supplemental reports from Dr. Astruc when the special master reopened the proceedings. Although the special master does discuss Dr. Astruc's report under a separate heading, it appears that he did so to distinguish the medical records submitted on remand from the medical records available to Special Master Abell and not because he had placed greater emphasis on Dr. Astruc's opinion than on those of the other physicians. Thus, the special master neither overstated the importance of Dr. Astruc's opinion nor disregarded the other available evidence.

CONCLUSION

The court has carefully considered petitioner's arguments and deems them without merit. The court concludes that the special master applied the correct legal standard and that he examined petitioner's medical records and reports and set forth his findings leading to his ultimate finding that petitioner had failed to provide preponderant evidence that the Hepatitis A vaccine caused petitioner's condition. Given the required deference to the special master's findings of fact, this court concludes that the decision denying compensation was not

arbitrary and capricious. Accordingly, petitioner's motion for review is denied, and the Clerk of the Court shall enter judgment in accordance with the special master's decision.

IT IS SO ORDERED.

No costs on review.

/s/ Christine O.C. Miller

Christine Odell Cook Miller
Judge